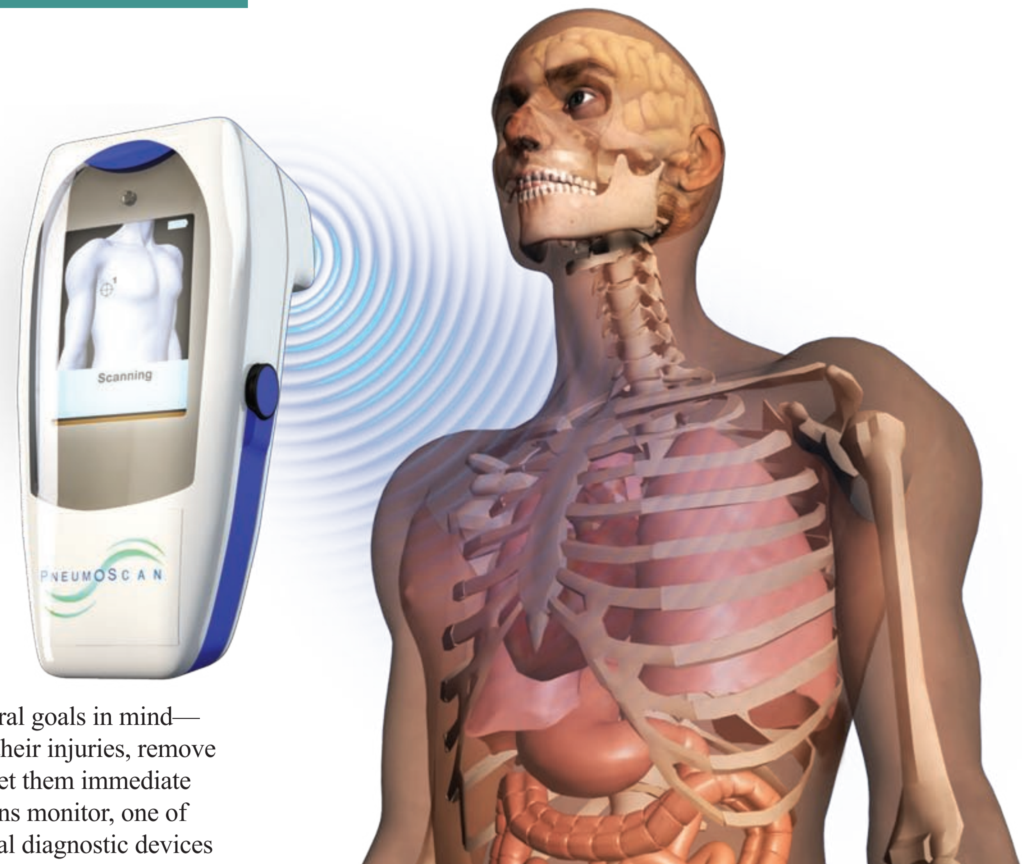
The Next Generation of Medical Diagnostic Devices



Livermore-developed handheld ultrawideband devices, such as the pneumothorax detector shown here, transmit and receive nonhazardous electromagnetic pulses that propagate through specific areas of the human body and are reflected by tissue, fluid, and air. (Rendering by Kwei-Yu Chu.)

AS search and rescue teams scour the rubble of fallen buildings, they have several goals in mind—locate the survivors, determine and stabilize their injuries, remove them from the hazardous environment, and get them immediate medical care. A Livermore-designed vital signs monitor, one of several ultrawideband- (UWB-) based medical diagnostic devices being developed at the Laboratory, can detect the respiratory rhythms of living individuals among the debris, expediting help from search and rescue personnel. Livermore's noninvasive pneumothorax (air trapped in the chest cavity) detector and intracranial hematoma (blood in the brain) detector could also offer first responders a quicker method for identifying life-threatening health conditions in emergency situations, thus improving a victim's chance of survival. Additionally, all three of these diagnostic tools could be tremendously beneficial to the future of patient care by providing an inexpensive means for continuous health monitoring. UWB technology makes them possible.

UWB signals are extremely short electromagnetic pulses (50 to 1,000 picoseconds) that are transmitted across a broad range of radio frequencies over several gigahertz. During the mid-1990s, Livermore scientists and engineers coupled a UWB antenna with an ultrafast digitizing laser diagnostic system to create an extremely low-power, high-fidelity system known as micropower impulse radar. (See *S&TR*, September 2004, pp. 12–19.) These systems transmit millions of UWB pulses in less than a second and then receive the signals when they are reflected off nearby objects. Funded in part by the Laboratory Directed Research and Development Program, engineer John Chang is working with scientists and engineers from Livermore and other research institutions to leverage this UWB technology for creating portable, noninvasive, nonhazardous medical diagnostic devices that can detect cardiac and respiratory conditions and thoracic and brain trauma.

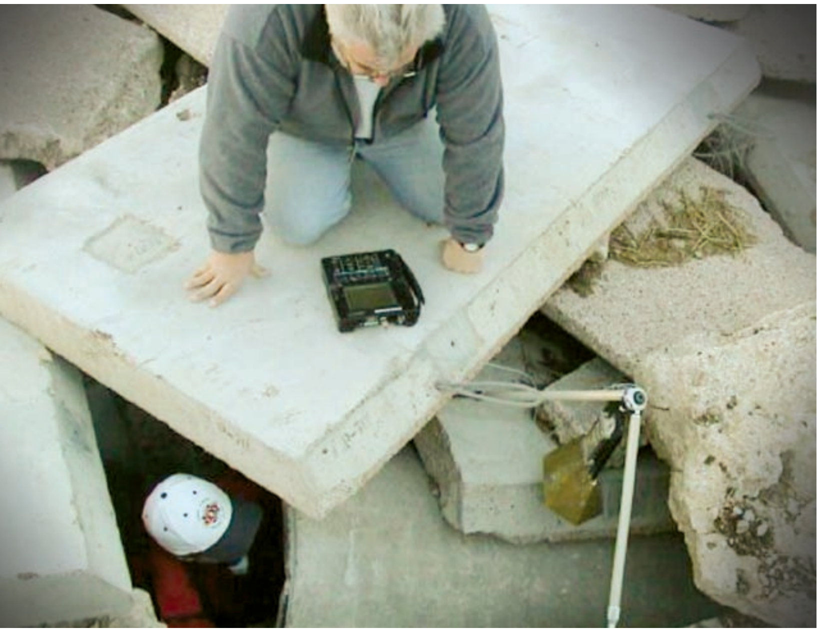
The vital signs monitor, pneumothorax detector, and intracranial hematoma detector are being developed as handheld devices that can be used outside of hospitals. They will complement existing medical diagnostic tools currently available only inside a hospital environment, such as computed tomography (CT), magnetic resonance imaging, and x-ray machines. UWB devices are also relatively more affordable and nonhazardous to human health. "Our noninvasive devices require no direct contact with the patient and emit only nonionizing radiation," says Chang, who leads the development effort. Livermore's medical diagnostic devices may become invaluable tools for first responders and could be further adapted for patients' in-home use.

Pulses in Time

Although the three devices have different designs and applications, the fundamental operation of each relies on effectively processing micropower UWB signals. A transmitter, or array of transmitters, inside the devices sends out directed UWB pulses. These extremely low-power electromagnetic signals can penetrate a variety of materials, such as human body tissue and fluids. Using various range-finding techniques, a receiver in the device captures these signals when they are reflected off an object within a preset distance over time. The received signals are digitized, processed, and stored in a computer. Reconstructive mathematical algorithms are used to analyze and interpret the data and can provide results in real-time.

The signals reflected back to the device vary from their original transmitted form. Their characteristics, such as frequency and resonance, are changed depending on the properties of the material with which they interact. Through extensive research and clinical trials on human subjects, the Livermore team has developed baseline data for each of the devices that indicate the differences between reflected signals from healthy patients and those suffering from specific health conditions, such as an intracranial hematoma. Each device correlates patient-specific data with these baselines, thus enabling users to detect abnormalities. “Through this research, we have a better understanding of how signals are characterized based on the physiological properties of materials,” says Chang.

Despite their intricate operation, Livermore’s medical diagnostic devices use very little power, operating on standard consumer batteries. Their low-power requirements and ability to transmit pulses in UWB make them resistant to background noise and unlikely to interfere with other electromagnetic equipment operating within the same time, frequency, and space. “Our devices are quite sensitive and can detect extremely subtle signatures in complex environments,” says Chang.



In prototype tests of the Livermore-developed vital signs monitor, engineer Patrick Welsh uses the device to successfully detect the respiratory rhythm of a person hidden underneath concrete debris.

A Two-Fold Purpose

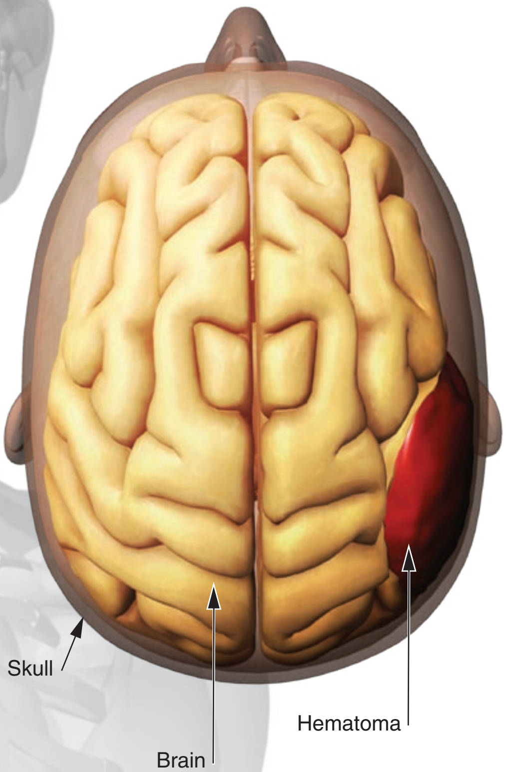
As a result of Livermore’s efforts, the vital signs monitor can be modified in form and function. It can be used as an electronic stethoscope that provides two key signatures corresponding to cardiac and respiratory vital signs. In another form, the device can detect the respiration of a victim trapped beneath collapsed structural debris. According to Chang, “The electromagnetic signals generated by this technology can penetrate through a broad range of materials, allowing us to determine not only the absence or presence of live humans underneath structural debris but also the state of health of any survivors.” A prototype device that incorporated hardware and signal processing capabilities was used as part of the concerted search and rescue efforts to look for survivors at ground zero of the World Trade Center following the September 11, 2001, attacks and in New Orleans after Hurricane Katrina in 2005.

How the device is operated in a given situation depends on the user’s needs. Whereas search and rescue teams would tap the device’s motion-sensing capabilities to locate survivors, emergency medical response personnel might use the device to determine whether a person is going into cardiac or respiratory failure. Under the oversight of Livermore’s Institutional Review Board, which ensures that all work by Laboratory staff involving human subjects meets appropriate regulations regarding subjects protection, studies revealed that rhythms obtained on the vital signs monitor directly correlated to data recorded from echocardiograms and pulse oximeters. “These studies have shown strong indications that this type of technology could be sensitive enough to eventually track cardiac arrhythmias,” says Chang. The Livermore team is currently evaluating how the technology could be used in long-term care environments such as dialysis centers and for telemedicine.

Dangerous Blood and Air

The intracranial hematoma and pneumothorax detectors are designed for diagnosing traumatic injuries to the head and chest. These types of injuries occur in combat and traumatic accidents. The intracranial hematoma detector identifies localized pools of blood underneath the skull that result from ruptured blood vessels. The pneumothorax device detects air trapped in the pleural area between the wall of the chest cavity and the lung. In both cases, immediate diagnosis is essential to prevent further complications and potentially even death, which can occur within minutes to hours under certain conditions. These devices could enable the fast triage and treatment decisions needed to save lives.

The intracranial hematoma detector has undergone its initial testing and has the potential to help a large number of people.



The intracranial hematoma detector can detect localized pools of blood located between the skull and the upper portion of the brain—an injury typically resulting from trauma to the head. (Rendering by Kwei-Yu Chu.)

"According to the Centers for Disease Control and Prevention, 1.4 million people per year in the U.S. sustain traumatic brain injuries," says Chang. This device could help medics in the field determine the size and location of a hematoma and if the condition is life-threatening. In addition, hospitals could use the device to monitor trauma patients in critical condition from their bedside rather than moving them every few hours for a CT scan. It also reduces patient exposure to the harmful ionizing radiation emitted by those scans.

The intracranial hematoma detector operates much like the vital sign monitor except that it receives UWB signals reflected off blood masses rather than off heart and lung tissues. Pooled blood is anomalous within the skull and has different dielectric properties than the surrounding healthy tissue or normal perfusing blood, so the characteristics of signals reflected off blood masses are notably different. The same is true for pneumothorax because air trapped in the chest cavity has different properties than the air processed normally through lung tissues.

The idea for the pneumothorax device came from Chang's 15 years of experience serving in the search and rescue community. Prior to the development of this device, medical responders would have to physically examine the patient for signs of respiratory distress, listen to their breathing with a stethoscope—a challenge in noisy environments—and then transport the patient to a hospital for a CT scan or chest x ray before positively identifying pneumothorax. With this new detector, medics on the scene can determine whether the patient has the condition and how much air is trapped, reducing the chance of exacerbating the already life-threatening condition. Patients can also use the device to monitor themselves from home if their condition is sufficiently mild and does not require hospital care.

The Laboratory received an R&D 100 Award for the technology in 2007 (see *S&TR*, October 2007, pp. 4–5), and the pneumothorax detector has completed initial clinical studies. Livermore has two Cooperative Research and Development Agreements and two commercial licenses with ElectroSonics Medical, Inc., formerly known as BIOMEC, Inc., for commercializing the technology. The company continues to work with the Laboratory to enhance the device and perform additional clinical studies. Livermore and ElectroSonics Medical were also selected for the 2009 Excellence in Technology Transfer Award, which is sponsored by the Federal Laboratory Consortium for Technology Transfer.

Remote Sensing

Future modifications to these devices will extend their capabilities for imaging purposes and further improve care in environments where medical resources are limited, such as in rural and combat areas. "The vital signs monitor is being modified so that it can be integrated into soldiers' protective gear for continuous monitoring," says Chang. This adaptation would allow commanders and medics to have a tool for monitoring a soldier's health remotely. "One advantage of all our devices is that direct skin contact is not required for an accurate reading." In addition, the Livermore team is working to modify the intracranial hematoma detector for detection and characterization of brain injuries unrelated to trauma, such as stroke.

Livermore's UWB technology has enabled the development of advanced medical technologies and provided mechanisms for improving patient care in almost every possible setting. "These devices could have a broad impact in environments where medical resources are limited or even nonexistent, whether it's on the Moon or next door," says Chang. UWB makes the devices possible; the Livermore team makes them a reality.

—Caryn Meissner

Key Words: intracranial hematoma detector, medical diagnostic device, micropower impulse radar, noninvasive pneumothorax detector, R&D 100, ultrawideband (UWB), vital signs monitor.

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